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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 22-IV-2008
C(2008)1680

NOT FOR PUBLICATION

COMMISSION DECISION

of 22-IV-2008

**amending the marketing authorisation for "Wilzin - Zinc acetate dihydrate",
a medicinal product for human use, granted by Decision C(2004)4056**

(ONLY THE FRENCH TEXT IS AUTHENTIC)

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COMMISSION DECISION

of 22-IV-2008

**amending the marketing authorisation for "Wilzin - Zinc acetate dihydrate",
a medicinal product for human use, granted by Decision C(2004)4056**

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹,

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93², and in particular the third subparagraph of Article 4(5) thereof,

Having regard to the notifications submitted by Orphan Europe S.a.r.l. under Article 4(1) of Regulation (EC) No 1085/2003,

Whereas:

- (1) The European Medicines Agency acknowledged, between 6 September 2007 and 6 March 2008, the validity of the notification(s) for minor variations of type IA, informing the marketing authorisation holder accordingly, and has prepared a list of the notification(s). The variation(s) took effect from the date of the communication from the European Medicines Agency concerning the validation.
- (2) The marketing authorisation should be updated, and Decision C(2004)4056 of 13 October 2004 amended accordingly.

¹ OJ L 136, 30.4.2004, p. 1, Regulation as last amended by Regulation (EC) No 1394/2007 (OJ L 324, 10.12.2007, p. 121).

² OJ L 159, 27.6.2003, p. 24.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)4056 is amended as follows:

1) The following list of notifications for minor variations is added to the updated marketing authorisation.

Application number	Scope (EU numbers affected)
EMEA/H/C/535/IA/04	1 (IA), 5 (IA) (EU/1/04/286/001-002)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Orphan Europe S.a.r.l., Immeuble Le Wilson, 70 Avenue du Général de Gaulle, 92800 Puteaux, France.

Done at Brussels, 22-IV-2008

For the Commission
Heinz ZOUREK
Director-General